

REMARKS

Claims 1-32 are pending in the present application.

The rejection of Claims 1-23<sup>1</sup> under 35 U.S.C. §112, first paragraph (enablement), is obviated in part by amendment and traversed in part.

At the outset, Applicants thank Examiner Roberts for the recognition that the present application enables a method for “ameliorating, progress blocking and therapeutically treating one or more stress induced diseases.” (see page 2, lines 20-22 of Office Action mailed August 24, 2007). With respect to the Examiner’s alleged lack of enablement for claims drawn to “preventing one or more stress induced diseases” (Claims 33-56 in the elected invention), Applicants make no statement with respect to the propriety of these allegations and in no way acquiesce to the same. Nonetheless, to expedite examination of the claims that the Examiner recognizes as being enabled, Applicants have canceled Claims 33-56 herein. Therefore, this ground of rejection is believed to be moot.

Applicants wish to thank Examiner Roberts for the indication in the Advisory Action mailed January 2, 2008, that this ground of rejection will be withdrawn in view of the amendments and remarks herein.

Applicants request withdrawal of these grounds of rejection.

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<sup>1</sup> Note: the Examiner improperly lists Claims 1-23 as being rejected. These claims do not recite “preventing”. The claims reciting this limitation are Claims 33-56.

The rejections of: (a) Claims 1-11, 13, 15-20, and 22-23 under 35 U.S.C. §102(b) over Schaefer et al, and (b) Claim 12 under 35 U.S.C. §103(a) over Schaefer et al, are respectfully traversed.

Applicants make no statement with respect to the propriety of the Examiner's continued allegations of antemortem stress qualifying as an emotion disorder (see Advisory Action mailed January 2, 2008) and in no way acquiesce to the same. Nonetheless, to expedite examination of this application only "emotion disorder" has been deleted from the claims.

Schaefer et al disclose a method of treating antemortem stress for livestock. The Examiner takes the position that "panic disorders and general anxiety disorders" embrace panic due to antemortem stress. The Examiner's alleges that "panic disorders and general anxiety disorders" are not defined in the specification, because "Applicant does not appear to give specific examples of what is encompassed by the disorders as they apply to animals such as cattle". Thus, the Examiner alleges that antemortem stress falls within the scope of either "panic disorders" and "general anxiety disorders" because antemortem stress is actually panic "because the animal is about to be slaughtered and therefore... antemortem stress is due to panic because the animal is aware it is in danger and therefore panics".

Applicants respectfully disagree with the Examiner's allegations and characterization of antemortem stress as being with in the scope of either "panic disorders" and "general anxiety disorders". Applicants submit that "panic disorder" and "general anxiety disorder" are art recognized terms and that the recognized definition for these terms would exclude "antemortem stress". To evidence the same, Applicants **submit herewith** KAPLAN & SADOCK'S, *Synopsis Of Psychiatry Tenth Edition*, (2007) Lippincott Williams & Wilkins. According to DSM-IV TR, diagnostic criteria for generalized anxiety disorder is shown in

Table 16.6-2 on page 624. The essential characteristics of “general anxiety disorder” are sustained and excessive anxiety and worry accompanied by a number of physiological symptoms. According to ICD-10, there must have been a period of at least 6 months with prominent tension, worry, and feeling of apprehension about every day events and problems (see Table 16.1-4 on page 585). In the diagnostic criteria for “panic disorder” of ICD-10, the panic attacks are not associated with marked exertion or with exposure to dangerous or life-threatening situations.

Schaefer et al define the term “antemortem stress” at column 3, lines 13-19 as:

The terms "antemortem period" and "antemortem stress", when used herein and in the claims, refer to the time and stresses imparted to animals during pre-slaughter treatment, including transport, holding, management, and handling. The terms are also meant to include stresses imparted during other animal marketing practices, such as transporting animals for other than slaughter purposes.

Clearly, the term “antemortem stress” as used in Schaefer et al is clinically distinct from “panic disorder” and “general anxiety disorder”. Therefore, Schaefer et al does not anticipate the claimed invention.

Applicants wish to thank Examiner Roberts for the indication in the Advisory Action mailed January 2, 2008, that this ground of rejection will be withdrawn in view of the amendments and remarks herein.

Withdrawal of this ground of rejection is requested.

The rejection of Claims 1-17, 20-23, 27, 30-47, and 52-56 under 35 U.S.C. §103(a) over Chen et al in view of Pitman is respectfully traversed.

The Examiner cites paragraph [0073] of Pitman for the administration of a combination of lycopene and lysine to certain subjects. However, in paragraph [0073] of Pitman subject #3 is described as having symptoms of memory loss and anxiety. Anxiety in Pitman does not qualify in the clinically recognized classes of individuals referred to by the term “anxiety disorders” in the present application. More specifically, as recognized by the Examiner, Pitman does not disclose or suggest anxiety disorders panic disorder or general anxiety disorder.

Recognizing this deficiency, the Examiner cites Chen et al and alleges that this reference discloses “anxiety disorders” at column 19, lines 35-61.<sup>2</sup> However, contrary to the allegation by the Examiner, Chen et al does not specifically disclose or suggest administering a composition containing lysine to treat anxiety disorders. The disclosure at column 19, lines 35-61 relates to the administration of compositions comprising  $\beta$ -interferon or variants thereof. No specific motivation is given to administer lysine together with  $\beta$ -interferon, much less for the treatment of anxiety disorders. Accordingly, Applicants submit that the combined disclosures of Chen et al and Pitman do not render the present invention obvious since, based on these references, the artisan would have been given no reason to administer the claimed composition for ameliorating, progress blocking, or therapeutically treating one or more stress-induced diseases specified in the claimed invention.

Despite the foregoing, in the Advisory Action mailed January 2, 2008, the Examiner alleges:

In regards to Chen in view of Pitman, Pitman discloses lysine to treat anxiety. Anxiety is a symptom of the recited disorders of Chen. Therefore

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<sup>2</sup> Apparently, improperly listed as column 19, lines 14-34.

it would have been obvious to one of ordinary skill in the art to have used lysine in the methods disclosed by Chen in order to treat the symptom of anxiety. This is further supported by cited precedent which recites, It is prima facie obviousness to select a known material based on its suitability for its intended use. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *in re Dial*, 326 F.2d 430.432 (CCPA 1964). Furthermore the primary reference specifically discloses lysine as a preferred amino acid for preparing the compositions of the reference and discloses anxiety disorders. The secondary reference supports the incorporation of lysine in treating anxiety disorders by disclosing lysine treats anxiety.

Applicants disagree.

The effective ingredient of the composition disclosed in Chen et al is a polypeptide such as IL-2 and IFN- $\beta$ , but not lysine and arginine. Those amino acids are added to the composition only for increasing storage stability of such a pharmaceutical composition (see Abstract and Example 1).

In addition, “memory loss and anxiety” disclosed in Pitman (paragraph 0073) is dementia-related symptoms (see Abstract), and completely different from “generalized anxiety disorder” of the present invention. To evidence the same, Applicants **submit herewith** KAPLAN & SADOCK’S, *Synopsis of Psychiatry Tenth Edition*, Lippincott Williams & Wilkins. “Dementia” is characterized by a variety of memory impairment including memory loss, but consciousness of the patient is not impaired. There are many causes of dementia, for example, brain tumor, head injury, stroke, Alzheimer’s type, etc.

According to the diagnostic standard of Dementia of the Alzheimer’s type (DSM-IV-TR), essential manifestations are both (1) memory impairment and (2) one or more of the following cognitive disturbances: (a) aphasia, (b) apraxia, (c) agnosia, and (d) disturbance in executive functioning (see page 335 of Kaplan & Sadock). These cognitive deficits cause significant impairment in social or occupational functioning and represent a significant

decline from a previous level of functioning. The course is characterized by gradual onset and continuing cognitive decline. These are main diagnostic standards of Dementia, and “anxiety” is not included in the diagnostic standard of Dementia of the Alzheimer’s type.

On the other hand, the essential characteristics of “anxiety disorder” such as panic disorder and generalized anxiety disorder, are sustained and excessive anxiety and worry accompanied by a number of physiological symptoms, including motor tension, autonomic hyperactivity, and cognitive vigilance (see, for example, page 580 of Kaplan & Sadock). The anxiety is excessive and interferes with other aspects of a person’s life. The anxiety is “a feeling of dread”, which commonly manifested by a variety of physiological symptoms of autonomic hyperactivity. This “feeling of dread” is different from “fear” that is a reaction to a dangerous object.

Thus, “memory loss and anxiety” is quite a different disorder from “anxiety disorder”, such as panic disorder and generalized anxiety disorder of the present invention.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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